- Personnel practices (e.g., gowning/de-gowning and training) and
- Other product specific requirements as applicable (e.g. sensitivity to light).

If API, API-product-contact packaging materials, or clean product-contact equipment are exposed to an environment, protective measures should be implemented or the environment should be controlled to eliminate or reduce the exposure to the environment. The protective measures can include consideration of the following:

- Protection of product contact packaging materials (e.g., drum liners, super-sacks) from the environment (e.g., keeping them covered);
- Protection of product contact equipment from the environment (e.g., by keeping equipment closed or covered);
- Elimination or reduction of the exposure to the environment (e.g., with use of continuous liners or down-flow booths); and
- Control of the environmental area to minimize the potential for contamination (e.g. enclosed rooms or booths with pressure differential).

For APIs exposed to the environment, the following facility design characteristics should be considered when evaluating the risk of impact on the API product:

- Potential contributors of viable and non-viable contamination (e.g., water, compressed gas systems, material of construction for product contact surfaces, architectural finish, sinks and floor drains);
- HVAC air quality, room pressurization and access arrangements, material and equipment storage;
- Personnel and material flows.

Room/area control strategy for Pressure Differentials, for areas where API products are exposed to the environment should be specified and documented, along with rationales.

Where determined to be critical, room/area pressure differentials should be controlled, monitored, and recorded. There should also be indication of function and failure (e.g., alarms) for critical pressure differentials.

When APIs are exposed to the environment, considerations for determining if temperature and humidity controls are critical to product quality should include:

- Product hygroscopicity;
- Product sensitivity to temperature and humidity;
- Product Specifications;
- Preclusion of condensate on room surfaces;
- Additional considerations such as operator comfort and equipment operation; and

For Exposed APIs where humidity and/or temperature are determined to be critical, the temperature and/or humidity should be controlled, monitored, and recorded. There should also be indication of

 